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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JOHN P. WHITE
COOPER AND DUNHAM LLP
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

RECEIVED
COOPER & DUNHAM
AUG 17 2001

PCT

WRITTEN OPINION

(PCT Rule 66)

1 mo Written opinion 9.14.01

Date of Mailing *(day/month/year)*	14 AUG 2001
Applicant's or agent's file reference: 59338-B-PCT	REPLY DUE within ONE months from the above date of mailing
International application No.: PCT/US00/14654	International filing date *(day/month/year)*: 26 MAY 2000
Priority date *(day/month/year)*: 28 MAY 1999 ✓	

International Patent Classification (IPC) or both national classification and IPC
Please See Supplemental Sheet.

Applicant
SYNAPTIC PHARMACEUTICAL CORPORTATION

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [X] Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV [ ] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [X] Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension., see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 28 SEPTEMBER 2001

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer FOZIA HAMIDI
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

Form PCT/IPEA/408 (cover sheet) (July 1998)*

WRITTEN OPINION

International application No.
PCT/US00/14654

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages (See Attached), as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the sequence listing part of the description:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

☒ contained in the international application in printed form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*

WRITTEN OPINION

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. (Please See supplemental sheet)

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _ are so unclear that no meaningful opinion could be formed *(specify)*.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. (See Attached) .

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

WRITTEN OPINION

International application No.
PCT/US00/14654

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Inventive Step (IS)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Industrial Applicability (IA)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO

2. citations and explanations

Claims 38-39, 42, 45 and 102 lack novelty under PCT Article 33(2) as being anticipated by EP 859,0551 A1 (SMITHKLINE BEECHUM CORP). EP 859,0551 document teaches an isolated polynucleotide encoding a G-protein coupled receptor,(see abstract and claims). The polynucleotide disclosed in this reference has a 28.5% homology to the polynucleotide with SEQ ID NO:5 of the present invention. See the copy of the comparison of SEQ ID NO:5 claimed in the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A'). Therefore, in the absence of recitation of the stringency conditions in claims 38-39, 42, 45 and 102 the polynucleotide taught by the EP 859,0551 reference would hybridize to the instant claimed polynucleotide of SEQ ID NO:5.

Claims 38-39, 42, 45 and 102 lack novelty under PCT Article 33(2) as being anticipated by EP 859,0551 A1 (The University of Sheffield). GB 2312211 A document teaches olignucleotides encoding human H2 receptor,(see abstract and SEQ ID NO:2 on pages 25-28). The olignucleotide disclosed in this reference has a 8.2% homology to the polynucleotide set forth in SEQ ID NO:5 of the present invention. See the copy of the comparison of SEQ ID NO:5 claimed in the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'B'). Therefore, in the absence of recitation of the stringency conditions in claims 38-39, 42, 45 and 102 the polynucleotide taught by the GB 2312211 A reference would hybridize to the instant claimed polynucleotide of SEQ ID NO:5.

Claims 1-9, 16-17, 19-25, 28-32, 35-36, 45-46, 118-119, 66-72, 77-87, 89-97, 99-101, 120-154, 159-168 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an isolated nucleic acid encoding a human SNORF33 receptor with the amino acid sequence set froth in SEQ ID NO:6, said nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:5 or a method of identifying compounds that specifically bind to said human SNORF33 receptor.

Claims 1-9, 16-17, 19-25, 28-32, 35-39, 42, 45-46, 66-72, 77-87, 89-97, 99-102, 118-154, 159-168 lack industrial applicability as (Continued on Supplemental Sheet.)

WRITTEN OPINION

International application No.
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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to adequately enable practice of the claimed invention because: the description fails to provide an enabling disclosure for claims that are drawn to "all" possible mammalian or human "snorf33" receptors. The description is enabling for an isolated nucleic acid comprising the polynucleotide sequence set forth in SEQ ID NO:5, encoding the polypeptide of SEQ ID NO:6, and a method of identifying compounds that bind to said polypeptide. The disclosure of the polynucleotide of SEQ ID NO:5 and the encoded receptor does not enable the skilled artisan to make and use all possible mammalian and human snorf33 receptors.

Claims 1-5, 16-17, 1-25, 28-32, 35-37, 45-46, 102, 118-119, 66-67, 77-96, 99-101 and 120-168 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not enabled as required under PCT Rule 5.1(a) for the reasons set forth in the immediately preceding paragraph.

WRITTEN OPINION

International application No.
PCT/US00/14654

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 10

Continuation of: Boxes I - VIII

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): C12N 15/12, 5/10; C12P 21/02; C07K 14/47, 14/705; G01N 33/53, 33/566, 33/567 and US Cl.: 435/69.1, 7.1, 7.2, 7.21, 71.1, 320.1, 471, 325, 334, 358, 361, 365, 368, 252.3, 255.1; 536/23.5; 530/350

I. BASIS OF OPINION:

This opinion has been drawn on the basis of the description:
page(s) 1-53, 55-197, as originally filed.
page(s) 54, filed with the demand.
and additional amendments:
NONE

This opinion has been drawn on the basis of the claims:
page(s) 198-200, 202-229, as originally filed.
page(s) none, as amended under Article 19.
page(s) 201, filed with the demand.
and additional amendments:
NONE

This opinion has been drawn on the basis of the drawings:
page(s) 1-28, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
NONE

This opinion has been drawn on the basis of the sequence listing part of the description:
page(s) 1-18, as originally filed.
pages(s) NONE, filed with the demand.
and additional amendments:
NONE

III. NON-ESTABLISHMENT OF OPINION:

The questions of whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect to claim numbers 10-15, 18, 26-27, 33-34, 40-41, 43-44, 47-65, 73-76, 88, 98, 103-117, 155-158.

No international search report has been established for claim numbers 10-15, 18, 26-27, 33-34, 40-41, 43-44, 47-65, 73-76, 88, 98, 103-117, 155-158.

V. 1. REASONED STATEMENTS:

The opinion as to Novelty was positive (YES) with respect to claims 1-9, 16-17, 25-32, 35-36, 45-46, 118-119, 66-72, 77- 87, 89-97, 99-101, 120-154, 159-168.
The opinion as to Novelty was negative (NO) with respect to claims 38-39, 42, 45, 102.
The opinion as to Inventive Step was positive (YES) with respect to claims 1-9, 16-17, 19-25, 28-32, 35-37, 45-46, 118-119, 66-72, 77-87, 99-101, 120-154, 159-168.
The opinion as to Inventive Step was negative (NO) with respect to claims 38-39, 42, 45, 102.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

The opinion as to Industrial Applicability was positive (YES) with respect to claims none.
The opinion as to Industrial Applicability was negative (NO) with respect to claims 1-9, 16-17, 19-25, 28-32, 35-39, 42, 45-46, 66-72, 77-87, 88-97, 99-102, 118-154, 159-168 .

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
defined by PCT Article 33(4). The polynucleotides and the polypeptides of instant claims are "orphans" in that no known biological activity has been attributed to them. There is little doubt that, after complete characterization, the instant polynucleotide of SEQ ID NO:5 and the encoded protein may be found to have a specific, substantial and credible utility. Thus, further characterization, is part of the act of invention and until it has been undertaken, the claimed invention is incomplete. The instant claims are directed to polynucleotide encoding a human SNORF33 receptor and methods of identifying compounds that bind to said receptor, however, there is no biological function or significance for these polypeptides or the polynucleotides encoding them, therefore, compounds that bind to said receptor would have no biological significance or utility. The description indicates that instant h SNORF33 receptor is an orphan G-protein-coupled receptor, but there is no disclosure ad to the biological significance or any functional characteristics of this receptor and the polynucleotide encoding it. Until some actual and specific significance can be attributed to the claimed polynucleotide and the encoded receptor, the instant invention is incomplete and does not possess industrial applicability. Since the description does not disclose a credible and "real world" use for the hSNORF33 receptor or the nucleic acid encoding it or compounds that bind to it, the claimed invention is incomplete and does not have industrial applicablity.

---------- NEW CITATIONS ----------
NONE